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January 10, 2020

The Honorable Frederic Block
The Honorable Vera M. Scanlon
U.S. District Court, Eastern District of New York
225 Cadman Plaza East
Brooklyn, NY 11201

Re: *Steele-Warrick v. Microgenics Corporation et al.*

Dear Judge Block and Magistrate Judge Scanlon:

Defendants Microgenics Corporation and Thermo Fisher Scientific Inc. ("Thermo Fisher") respectfully request a pre-motion conference to seek permission to file a Rule 12 motion to dismiss Plaintiff's putative class-action Complaint and to strike the class allegations.

Plaintiff's claims arise from events that occurred while she was in the custody of the New York Department of Corrections and Community Supervision ("DOCCS"). As alleged in the Complaint, prison officials screened Plaintiff's urine for illicit substances, using an Indiko Plus urinalysis analyzer supplied by Microgenics, and the "results came back positive" for buprenorphine, even though she contends she had not taken buprenorphine. Compl. ¶ 28.

Plaintiff pleaded not guilty to an ensuing drug-use charge, and a three-day hearing was held at which Plaintiff introduced testimonial and documentary evidence. *Id.* ¶ 32, 42–43. A hearing officer found Plaintiff guilty; she was sentenced to eleven days in keep lock and "thirty days loss of recreation, packages, and commissary privileges," which she alleges caused adverse "mental and emotional effects" that "cannot be understated." *Id.* ¶¶ 44-45, 52.

Plaintiff blames Defendants for the DOCCS's decision to discipline her. Pleading a single count of negligence, Plaintiff demands damages for herself and a putative class of "all persons who obtained positive testing results" for buprenorphine "generated by Indiko Plus urinalysis analyzers while in DOCCS custody in 2019." Compl. ¶ 62. Specifically, she contends that Microgenics entered into a contract with the DOCCS to supply analyzers to fifty-two New York correctional facilities. *Id.* ¶¶ 14–15. Based on that undertaking and on Thermo Fisher's purported role as manufacturer of the analyzers and owner of the immunoassays used in the analyzers, Plaintiff alleges Defendants owed her a duty to ensure the "analyzers produced accurate and reliable" results. *Id.* ¶ 76. Because the analyzers allegedly returned "false positives," Plaintiff claims Defendants breached their purported duties. *Id.* ¶ 77. Plaintiff does *not* allege that Defendants played a role in conducting her drug screen or in her disciplinary proceedings.

A so-called "false positive" is a potential outcome of any urinalysis drug screen by immunoassay. As noted in the Indications for Use ("IFUs") that accompany the Microgenics-

supplied assay for buprenorphine, a screen "provides only a preliminary analytical test result" and a "more specific alternative chemical method must be used to obtain a confirmed analytical result." Indications for Use, https://www.accessdata.fda.gov/cdrh_docs/pdf16/K163101.pdf.

1. The Complaint fails to state a claim for relief against Microgenics.

Under New York law, a plaintiff alleging negligence must plead and prove that the defendant "owed . . . a specific duty to him or her." *Hamilton v. Beretta U.S.A. Corp.*, 750 N.E.2d 1055, 1060 (N.Y. Ct. App. 2001). Here, Plaintiff premises her claim against Microgenics on an alleged duty arising from Microgenics's contract with the DOCCS. Compl. ¶¶ 14, 16, 76. But subject to only a few limited exceptions, a contractual obligation, standing alone, will generally not impose a tort duty in favor of a third party to the contract. *Espinal v. Melville Snow Contractors, Inc.*, 773 N.E.2d 485, 488 (N.Y. Ct. App. 2002).

Consistent with this no-duty rule, the New York Court of Appeals has recognized a tort duty running from drug-screen contractors to third parties only in narrow circumstances not present here. In *Landon v. Kroll Laboratory Specialists, Inc.*, the court held that a drug-screen *laboratory* retained by a probation department owed a duty to probationers to perform "drug test[s] in keeping with relevant professional standards." 999 N.E.2d 1121, 1125 (N.Y. Ct. App. 2013). In reaching that conclusion, the court noted that a laboratory that conducts a screen is "in the best position to prevent false positive results," *id.* at 1124, and emphasized the plaintiff's allegations that the laboratory failed to comply with established test standards, including that positive screens should be confirmed by another test method, *id.* at 1123–25. And in a subsequent decision, the court clarified that its holding "was limited to 'th[o]se circumstances'—namely, a drug laboratory's failure to adhere to professionally accepted scientific testing standards." *Pasternack v. Lab. Corp. of Am. Holdings*, 59 N.E.3d 485, 490 (N.Y. Ct. App. 2016) (citation omitted).

Here, the Complaint does not allege facts sufficient to give rise to a tort duty under *Landon* and *Pasternack*. While Plaintiff alleges that Microgenics contracted to supply analyzers and training to the DOCCS, she does not contend that Microgenics is a laboratory or that it conducted her drug screen. Counsel are not aware of any court in any jurisdiction holding that a drug-screen-equipment supplier—as opposed to a drug-screen laboratory—owes a tort duty directly to the persons who are screened. Furthermore, and in stark contrast to the plaintiff in *Landon*, Plaintiff does not allege that Microgenics violated any professional, industry, government, or other standards in performing its contractual obligations to the DOCCS.

Moreover, the Complaint fails to plausibly allege breach of any purported duty. Plaintiff alleges in conclusory fashion that Microgenics failed "to ensure that the . . . analyzers yielded accurate and reliable test results." But she does not allege how or why the analyzers supposedly failed to produce accurate results. Compl. ¶ 77. She does not, for instance, identify any alleged defects in the products' designs or any inadequacies in the services Microgenics provided. Plaintiff's bald assertions of breach do not suffice. *See Farash v. Cont'l Airlines, Inc.*, 337 F. App'x 7, 9 (2d Cir. 2009) (conclusory allegations about how defendant was negligent are insufficient); *Quintana v. B. Braun Med. Inc.*, No. 17-cv-06614, 2018 WL 3559091, at *3 (S.D.N.Y. July 24, 2018) (dismissing a design-defect claim because the complaint did not allege a specific defect).

2. Independently, the Complaint fails to state a claim against Thermo Fisher.

Plaintiff does not allege that Thermo Fisher entered into contract with the DOCCS. She instead bases her claims against Thermo Fisher on her contentions that Thermo Fisher manufactured the analyzers and owns the assays used in the analyzers, contentions Thermo Fisher denies. Compl. ¶ 10. Plaintiff claims that, as the purported manufacturer, Thermo Fisher owed a duty to ensure the analyzers returned "accurate and reliable" results. Compl. ¶ 76. But a manufacturer's duty is to "exercise reasonable care so as to avoid the occurrence of injuries by any product which can reasonably be expected to be dangerous if negligently manufactured or sold." *Gebo v. Black Clawson Co.*, 703 N.E.2d 1234, 1238 (N.Y. Ct. App. 1998) (citation omitted). Thus, to plead a viable claim, a plaintiff "must allege that the [product] was unreasonably dangerous for its intended use." *McCarthy v. Olin Corp.*, 119 F.3d 148, 155 (2d Cir. 1997).

Here, Plaintiff does not allege that the analyzers or assays are unreasonably dangerous. Nor could she do so, as the analyzers and assays pose no risk of physical injury and provide only preliminary analytical test results. Plaintiff therefore has not plausibly alleged that Thermo Fisher owed her a duty. *See, e.g.*, *S.F. v. Archer-Daniels-Midland Co.*, No. 13-cv-634S, 2014 WL 1600414, at *7 (W.D.N.Y. Apr. 21, 2014) (dismissing products liability claims where the plaintiff failed to plausibly allege the product was unreasonably dangerous).

Further, as to the issue of breach, Plaintiff rests on precisely the same conclusory, legally insufficient allegations that imperil her claim against Microgenics. Compl. ¶ 77; *see supra* at 2.

3. Plaintiff's class allegations must be struck.

Although generally disfavored, a motion to strike class allegations is proper where the plaintiff's allegations demonstrate "it would be impossible to certify the alleged class regardless of the facts the plaintiffs may be able to obtain during discovery." *Greene v. Gerber Prods. Co.*, 262 F.Supp.3d 38, 52 (E.D.N.Y. 2017). Here, the impropriety of certification is facially apparent.

First, the broad class defined in the Complaint incorporates "all persons who obtained positive testing results," including those who obtained true positive results. Compl. ¶ 62. Persons who received true positive results have no injury, and absent an "injury in fact," such persons lack standing to sue. *See Denney v. Deutsche Bank AG*, 443 F.3d 253, 263–64 (2d Cir. 2006) ("[N]o class may be certified that contains members lacking Article III standing.").

Second, mass tort cases are "ordinarily not appropriate for class treatment," as they present "significant questions . . . affecting the individuals in different ways." *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 625 (1997) (citations omitted). Here, Plaintiff's allegations highlight numerous individualized questions that would predominate in any class-wide proceeding: To recover, each plaintiff would need to present evidence about how his drug screen was performed; the medications and other substances he was taking at the time; the course and effects of any disciplinary proceedings; and the genuineness and extent of any purported emotional harm. Those individualized inquires would overwhelm any hypothetical common questions of law or fact. In sum, this is a case in which the Court should rule at the outset that class treatment is improper.

Sincerely,

Christopher R. Carton